REMARKS

Claim Objections

The objections of claims 1, 2 and 4 are believed to be moot in view of the current claims.

The Rejection under 35 U.S.C. §103

The rejection of claims 1-26 under 35 U.S.C. §103 as being unpatentable over Cygnus (WO 96/40087) and Lipp (U.S. Patent No. 5,676,968) both in view of Schollkopf et al. (US 5,827,842) or vice versa al in further view of Hansen et al. (US 5,120,546) is respectfully traversed.

Schollkopf et al. discloses bridged norprogesterone derivatives, preferably for oral administration (see col.6 line13), including the compound recited in the claims. At col. 6, lines 29-31 Schollkopf suggests that it is possible to incorporate the broad class of disclosed substances into a transdermal system, although there is no guidance of which specific transdermal matrix to choose from or any other guidance of available classes of transdermal systems.

Applicant's transdermal system is based on a specific matrix, polyacrylate. Considering the myriad of possible matrix adhesives one skilled in the art would have to choose from after searching available disclosures, Schollkopf totally fails to motivate choice of a polyacrylate matrix.

As previously noted, the mere fact that the Cygnus (general acrylate system) or Lipp (use of crystallization inhibitors) references employ other gestagens in their acrylate transdermal systems does not render the claims obvious. In fact, the only guidance a skilled worker would take away from these references as to which gestagens are useful with acrylate systems is Lipp's teaching away from use of the active ingredient of the invention (See col. 2, lines 48-59):

> Active ingredients, which are suitable for the production of transdermal systems according to the invention, are preferably those that are poorly soluble or insoluble in usual adhesive systems and crystallize well, such as, for example, steroid hormones, such as: gestagenically effective steroid hormones, such as...

Cygnus only mentions two specific gestagens in claim 7. There is no suggestion that any other gestagens can be used

The highly potent gestagen contained within applicant's polyacrylate matrix system has a high solubility of up to about 20%. Thus, this combination of prior art does not lead to a selection of applicant's gestagen for use in polyacrylate systems.

As is disclosed in the specification on page 6, extraordinarily high transdermal flows can be achieved by such a combination. This property is unique. With regards to transdermal systems, different gestagens have different behaviors. They are not freely interchangeable. The gestagens disclosed in the prior art for transdermal systems generally have relatively low solubilities in the matrices used or have higher solubilities but then have low potency. This invention uses a high potency gestagen in a polyacrylate matrix and achieves a high transdermal flow. Example 3 of applicant's specification compares the transdermal skin flow of gestodene (disclosed in examples 5 and 6 of Lipp) and hydroxytrienedione. As graphically depicted in figure 2, the skin flows for 1% matrix transdermal systems between hydroxytrienedione and gestodene are comparable. However, gestodene loading cannot increase above about 1% without resulting in a recystalization phenomenon (page 14, line 17) and thus the skin flow of gestodene cannot exceed values achieved at 1%. Figure 2 further depicts examples of TDS systems loaded with from 3- 15 % Hydroxytriendedione. They very clearly show a much higher skin flow then the highest achievable levels for gestodene.

Hansen US 5,120,546 merely discloses a large group of components which may be included within transdermal systems, and adds nothing to the forgoing.

Thus, in light of the above remarks, the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

Respectfully submitted,

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